510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:
K040603

B. Purpose for Submission:
The original 510(k) Premarket notification K030531 was submitted by Medtronic MiniMed and received clearance on June 17, 2003. As previously discussed with the Office of IVD, the purpose of this 510(k) is to obtain a separate clearance for Becton Dickinson Diabetes Care. This 510(k) references the original cleared 510(k) K030531 for technical information such as bench testing, software development description, EMC testing.

C. Manufacturer and Instrument Name:
Paradigm Link Blood Glucose Monitor.

D. Type of Test or Tests performed:
Glucose (self testing) Quantitative

E. System Descriptions:

1. Device Description:
   The BD Paradigm LinkTM Blood Glucose Monitor is a handheld battery (3V) operated device intended for use in the quantitative measurement of glucose in capillary blood collected from fingertips. The BD Paradigm LinkTM Blood Glucose Monitor may be used as a stand alone blood glucose meter or used in conjunction with Medtronic MiniMed External Insulin Pumps when configured for RF telemetry.

   The BD Paradigm LinkTM Blood Glucose Monitor is the result of simple design modifications to the commercially available BD LogicTM Blood Glucose Monitor (K022581). The design modifications, hardware and software, provide Radio Frequency (RF) communication (wireless communication) between the BD Paradigm LinkTM Blood Glucose Monitor and specific MiniMed external insulin pumps. The RF circuitry and embedded software used in the BD Paradigm LinkTM is the same as that used in the MiniMed Paradigm 511 External Insulin pump. The MiniMed Paradigm 511 External Insulin Pump was described in K011829 and received FDA clearance on August 18, 2000.

   The Paradigm LinkTM wireless communication feature allows the user to automatically send a blood glucose value to the MiniMed 512 external insulin pump. The blood glucose value sent to the MiniMed 512 Pump may be used in the pump's Bolus Wizard. The Bolus Wizard is a user interactive feature that suggests an insulin dose based on a blood glucose value, insulin sensitivity, carbohydrates to insulin ratio and the carbohydrate content of the current meal. The direct RF transmission of the blood glucose value from the meter to the pump reduces the potential for user to misread or incorrectly

enter blood glucose test result The MiniMed 512 External Insulin Pump and the Bolus Wizard were described in the original 510(k) Premarket Notification (K030531) submitted on 2/14/03. Reference the original submission for a description of the MiniMed 512 External Insulin Pump and the Bolus Wizard.

The wireless communication feature also allows the user to utilize the BD Paradigm LinkTM as a communication device to download device information from MiniMed external insulin pumps (model no. 511 and higher) to a PC. Currently, the user can download device information using the MiniMed ComLinkTM. The MiniMed ComLinkTM was described in K021974, which received FDA clearance on August 6, 2002. The ComLinkTM hardware consists of a radio-frequency (RF) transceiver and a single female RS-232 compatible serial communications port.

Identical to the ComLinkTM, data is downloaded from an external insulin pump to a PC via the Paradigm LinkTM using RF telemetry. In addition, the BD Paradigm LinkTM RF communication protocol to allow pump/meter/PC RF communication is a replica of the ComLinkTM. The BD Paradigm LinkTM is connected to a PC using the BD USB Interface Cable (K023219). Reference figure 111.1 for an overview of PC data download configuration. The BD Paradigm LinkTM Blood Glucose Monitor kit consists the following components:

- BD Paradigm LinkTM Blood Glucose Monitor
- BD Test Strips
- BD Ultra-Fine 33 Lancets
- BD Lancet Device
- BD Control Solution
- labeling

The BD Test Strips, BD Control Solution and lancet devices were described in the BD Logic 5 10(k) Premarket Notification, K022581.

2. Principles of Operation:
   Employs amperometric technology to measure the glucose concentrations in the blood sample by measuring the amount of current that is generated and flows through the electrodes on the test strip.
3. Modes of Operation:
   Uses 0.3 uL of capillary whole blood to fill the sample chamber
4. Specimen Identification:
   Time and date of test
5. Specimen Sampling and Handling:
   Self testing capillary blood from fingerstick
6. Calibration:
   Lot Specific coded calibration
7. Quality Control:
   Control Solution were described in the BD Logic 510(k) Premarket Notification, K022581

8. Software:

   FDA has reviewed the applicant's Hazard Analysis and software Documentation: Yes __X__ or No _____ (K030531)

F. Regulatory Information:

1. Regulation Section:
   21CFR §862.1345 -Glucose test system.
2. Classification:
   2
3. Product Code:
   NBW
4. Panel:
   CH

G. Intended Use:

1. Indication(s) for Use:
   The BD Paradigm Link Blood Glucose Monitor is intended to be ue for the quantitative measurement of glucose in whole blood. It is intended for use by people with diabetes mellitus in the home as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

   The BD Paradigm Link Blood Glucose Monitor is specifically indicated to the quantitative measurement of glucose in whole blood samples obtained from the fingertip.
2. Special Condition for use Statement(s):

H. Substantial Equivalence Information:

1. Predicate device name(s)and 510(k) numbers:
   BD Logic Blood Glucose Monitor (K022581)

2. Comparison with Predicate Device:

Predicate Device Comparison

	Paradigm Link™ Principal Device	BD Logic™ Blood Glucose Monitor Predicate Device, K022581
Intended Use	The Paradigm Link™ Blood Glucose Monitor is intended for quantitative measurement of glucose in whole blood. It is intended for use by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes mellitus and is not intended for use on neonates.	The BD Logic™ Blood Glucose Monitor is intended for quantitative measurement of glucose in whole blood. It is intended for use by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes mellitus and is not intended for use on neonates.
System components	• Meter • Test Strips • Normal Control Solution • Lancing Device and lancets	• Meter • Test Strips • Normal Control Solution • Lancing Device and lancets
Test Method	Glucose oxidase/Amperometric detection	Glucose oxidase/Amperometric detection
Test Strip Calibration	Manual	Manual
Sample	Capillary Whole Blood	Capillary Whole Blood
Test Strip Volume	0.3 µl	0.3 µl
Sample application	End of strip capillary draw	End of strip capillary draw
Test range	20 - 600 mg/dl	20 - 600 mg/dl
Test time	5 seconds	5 seconds
Hematocrit range	25 - 60%	25 - 60%
Temperature range	59 F to 102 F	59 F to 102 F
Relative Humidity	10 – 90 %	10 – 90 %
Altitude	Up to 10,000 ft	Up to 10,000 ft
Memory	Up to 250 glucose and control results Up to 250 Insulin records	Up to 250 glucose and control results Up to 250 Insulin records
Data Port	Yes	Yes
Pump to PC Communication via meter/USB:	No	Yes
RF Data Transfer of Glucose Result:	No	Yes
Communication Device	Yes	Yes
For use with Minimed External Insulin Pumps	Yes	Yes
RF telemetry technology	Yes	Yes
PC Connection	USB	Serial
Acts a conduit for data download	Yes	Yes
Operate at a 916.5 MHz RF frequency	Yes	Yes
Comply with EN/ISO and FCC standards for EMI/EMC, safety, and RF devices	Yes	Yes

I. Standard/Guidance Document Referenced (if applicable):

See Premarket Notification (K030531)

J. Performance Characteristics:

1. Analytical Performance:
   - *a. Accuracy:*
     Not Applicable
   - *b. Precision/Reproducibility:*
     Not Applicable

c. Linearity:
Not Applicable
d. Carryover:
Not Applicable
e. Interfering Substances:
Not Applicable

2. Other Supportive Instrument Performance Data Not Covered Above:
None

K. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.